Claims

1. A composition for assisting mucus clearance, the composition comprising one or more mucoactive agents for reducing cross-linking within the mucus; for diluting the mucus; and/or for digesting naked DNA and cell debris within the mucus.

2. A composition as claimed in claim 1, wherein one or more of the mucoactive agents are able to reduce inflammation.

3. A composition as claimed in claim 1 or 2, comprising two or more mucoactive agents.

4. A composition as claimed in any one of the preceding claims, wherein the mucoactive agent or agents reduce cross-linking within the mucus and dilute the mucus.

5. A composition as claimed in any one of the preceding claims, comprising one or more glycosaminoglycans.

6. A composition as claimed in claim 5, wherein the glycosaminoglycan is heparin and/or a heparinoid.

7. A composition as claimed in claim 6, wherein the heparinoid is danaparoid sodium, or dermatan sulphate.

8. A composition as claimed in claim 6, wherein the heparinoid contains heparin, dermatan sulphate and chondroitin sulphate.

9. A composition as claimed in any one of the preceding claims, comprising sulfated glucosaminoglycans, glycosaminoglycan polysulphate compounds, or sulfated mucopolysaccharides.

10. A composition as claimed in any one of the preceding claims, comprising a monosaccharide, a disaccharide and/or an oligosaccharide.

11. A composition as claimed in any one of the preceding claims, comprising dextran, dextrin, glucose and/or mannitol.

12. A composition as claimed in any one of the preceding claims, comprising an amino acid.

13. A composition as claimed in any one of the preceding claims, comprising rhDNase, gelsolin and/or thymosin ß4.

14. A composition as claimed in any one of the preceding claims, comprising acetylcysteine and/or Nacystelyn.

15. A composition as claimed in any one of the preceding claims, wherein the composition is a dry powder for pulmonary inhalation.

16. A composition as claimed in claim 15, wherein the composition has a fine particle fraction (<5µm) of at least 50%, and preferably between 70 and 99% or between 80 and 99%.

17. A composition as claimed in claim 15 or claim 16, wherein the composition has a fine particle dose of between 50 and 90%, and preferably between 60 and 70%.

18. A composition as claimed in any one of claims 15-17, comprising particles of at least one mucoactive agent and a force control agent.

19. A composition as claimed in claim 18, wherein the force control agent is an amino acid or peptide, or derivatives thereof, a phospholipid or a metal stearate.

20. A composition as claimed in claim 19, wherein the force control agent is leucine, lysine, cysteine, or mixtures thereof.

21. A composition as claimed in claim 18, wherein the force control agent is included in an amount of up to 50% w/w, preferably less than 10% w/w, and more preferably less than 5% w/w.

22. A composition as claimed in any of claims 15-21, wherein the composition comprises particles of mucoactive agent having a MMAD of less than 10μm.

23. A composition as claimed in claim 22, wherein the particles of mucoactive agent have a MMAD of 2-5μm.

24. A composition as claimed in any one of claims 15-23, wherein the composition further comprises carrier particles, preferably wherein the carrier particles have a particle size of at least 20μm.

25. A pharmaceutical composition as claimed in any one of claims 1-24, for use in therapy.

26. A pharmaceutical composition as claimed in claim 25, for treating a pulmonary disease.

27. A pharmaceutical composition as claimed in claim 26, wherein the pulmonary disease involves hypersecretion of mucus or abnormal viscoelasticity of mucus.

28. A pharmaceutical composition as claimed in either of claims 26 or 27, wherein the pulmonary disease is chronic bronchitis, acute asthma, cystic fibrosis (CF), chronic obstructive pulmonary disease (COPD) or bronchiectasis.

29. A method of treating a pulmonary disease comprising the administration of a therapeutically effective amount of a pharmaceutical composition as claimed in any one of claims 1-24 to a subject in need of such treatment.

30. A method of producing particles for use in a composition as claimed in any one of claims 1-24, the method comprising spray drying the one or more mucoactive agents.

31. A method as claimed in claim 30, wherein the spray drying involves the use of a spray drier comprising a means for producing droplets moving at a controlled velocity.

32. A method as claimed in claim 31, wherein the velocity of droplets at 5mm from their point of generation is less than 20m/s.

33. A method as claimed in claim 31 or 32, wherein the spray drier comprises an ultrasonic nebuliser.

34. A method as claimed in any one of claim 31-33, wherein the one or more mucoactive agents are co-spray dried with a force control agent

35. A method of producing particles for use in a composition as claimed in any one of claims 1-24, the method comprising jet milling particles of the one or more mucoactive agents in the presence of air or a compressible gas or fluid.

36. A method as claimed in claim 35, wherein the particles are jet milled in the presence of a force control agent.

37. A method as claimed in any one claims 35 and 36, wherein the jet milling is carried out at an inlet pressure of between 0.1 and 3 bar.

38. A method as claimed in any one of claims 35 and 36, wherein the jet milling is carried out at an inlet pressure of between 3 and 12 bar.

39. A method as claimed in any one of claims 35-38, wherein at least 90% by volume of the active particles are less than 20μm in diameter prior to jet milling.

40. A method as claimed in any one of claims 30-39, wherein 90% of the resulting dried particles have a size of less than 10μm, as measured by laser diffraction.